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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF  
KIS ET AL.

APPLICATION NO: Not Yet Assigned

FILED: Herewith

FOR: PACKAGE FOR A PHARMACEUTICAL PRODUCT AND METHOD  
OF STERILIZING THE PACKAGE

Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above-referenced patent application, please amend the application as follows.

IN THE CLAIMS:

Please cancel claims 1 to 14.

Please substitute the claims set out below under the heading "Clean Copy of the Claims" for the pending claims.

## CLEAN COPY OF THE CLAIMS

15. (New) A package for a pharmaceutical product wherein said package is made of polypropylene and wherein said package, after autoclaving at at least 121°C and for at least 20 minutes, suffers no deformation, does not shrink, and does not explode, and wherein said package retains a sufficiently high squeezability to dispense said product.

16. (New) A package according to claim 15, wherein said package meets the requirements of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997) and the European Union regulation.

17. (New) A package according to claim 15 wherein said package comprises a plastic bottle for holding said product to be dispensed, a plastic nozzle tip for dispensing said product, and a cap for closing said bottle, wherein said bottle has walls that have a wall-thickness.

18. (New) A package according to claim 17, wherein said bottle comprises a neck portion that includes an externally threaded portion and an outer rim which defines an outlet of the bottle, wherein said nozzle tip is in fluid contact with said outlet of said bottle and wherein said nozzle tip has a dispensing pathway in fluid communication with an outlet, and wherein said cap has internal threads for engagement with said externally threaded portion of said neck portion of said bottle.

19. (New) A package according to claim 17, wherein said bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260 or of low density polyethylene.

20. (New) A package according to claim 17, wherein said bottle has a bottom portion, and said bottom portion of said bottle has a concave configuration.

21. (New) A package according to claim 17, wherein said bottle has a wall-thickness in the range of 0.3 mm to 0.6 mm.

22. (New) A package according to claim 21, wherein said wall-thickness is 0.45 mm.

23. (New) A package of claim 17, wherein the physical chemical properties of said polypropylene meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997).

24. (New) A package of claim 19, wherein the physical chemical properties of said polypropylene meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997).

# REMARKS

By this amendment, claims 1 to 14 are canceled, and new claims 15 to 24 are added. The new claims are supported by claims 1 to 14 as originally filed, and by the specification. No new matter has been added.

An early and favorable examination on the merits is respectfully requested.

Respectfully submitted,



David E. Wildman  
Attorney for Applicants  
Reg. No. 40,226

Novartis Corporation  
Patent and Trademark Dept.  
564 Morris Avenue  
Summit, NJ 07901-1027  
(908) 522-6946

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